DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 25, 2002

ANDA 010228

Gambro BCT Inc.
Attention: William H. Duffell, Sr.
10811 West Collins Avenue
Lakewood, Colorado 80215-4440

Dear Mr. Duffell:

Please refer to your abbreviated new drug application (ANDA) dated January 15, 2001, received February 28, 2001, submitted under section 505(j)/pursuant to section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act for Anticoagulant Citrate Dextrose Solution Formula A.

We acknowledge receipt of your submission dated October 1, 2001 and received October 3, 2001. Your submission of October 1, 2001 constituted a complete response to our August 27, 2001 Not Approvable letter.

We have completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the immediate container draft labels submitted on February 12, 2002. Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* (January 1999). (http://www.fda.gov/cder/guidance/2353fnl.pdf) Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but not more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved ANDA 980728." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

If you have any questions, contact Richard Potter, Senior Regulatory Operations Officer, at 301-827-6156.

Sincerely, yours,

Mark Weinstein

Mark Weinstein, Ph.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research